Appendix C: REQUEST FOR HUMAN SUBJECTS EXEMPTION FOR ATP PROPOSALS -- BIOLOGICAL STUDIES

The following information must be supplied along with the Proposal to allow for NIST/ATP to have an independent evaluation performed of a possible exemption from 15 CFR Part 27, Protection of Human Subjects. **Proposers are reminded that the term data includes collection of data from voice, video, digital or image recordings made for research purposes.** Proposals that include collecting data or otherwise using informatics are referred to Appendix D.

1. What is the timeframe (start and end dates) for human tissue/subject involvement?
2. State the technical justification for human tissue/subject involvement (i.e. No other way to achieve equivalent technical outcome? Why?).
3. Are the samples stripped of any identifiable information (e.g. personal identifiers such as names or codes which can be traced back to the human donor or source)? Explain.
4. Is the tissue publicly available from a named source? Explain and name the source(s) being considered or planned, if appropriate.

   NOTE: An answer of "no" to either question #3 or #4 may disqualify the project from an exemption. In those cases, an appropriate IRB approval may be required, and should accompany the proposal if the work is within the first year of the project.

5. What is the anatomical source of the cell or tissue? (e.g. liver, skin, etc.)
6. What is the extent of tissue handling by the Principal Investigator: collecting, receiving, and/or sending specimens?
7. Are the samples pre-existing, being collected for the express purpose of the research, or obtained by some combination of the two?
8. Do the samples come from individuals who may need special safeguards (i.e. minor children, pregnant women, human in vitro fertilization, fetuses, or prisoners)?

   NOTE: An answer of "yes" to question #8 disqualifies the project from exemption under 15 CFR Part 27. In these cases, the proposal protocol/task descriptions MUST be reviewed and approved by an IRB that possesses a current assurance, appropriate for the research in question, on file with the Office of Protection from Research Risks (OPRR) of the Department of Health and Human Services, and which has been approved by OPRR for federalwide use. This IRB approval MUST accompany the proposal at submission.

9. Has the research been reviewed by an IRB? If yes, attach a copy of the review.

The following signed statement must accompany the answers to the above questions:

This is an accurate description of the proposed research involving human subjects/tissues. Any changes in protocol or task descriptions will be submitted in advance to the IRB as appropriate, and to the ATP prior to notification of ATP award decisions.

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Signature, Principal Investigator Date